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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,755

02/28/2002

Yoshimitsu Iida

IIDA=20

3713

1444

7590

08/23/2002

BROWDY AND NEIMARK, P.L.L.C.
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EXAMINER

NGUYEN, HELEN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/069,755

Applicant(s)

IIDA ET AL.

Examin r

Helen Nguyen

Art Unit

1617

-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

DETAILED ACTION

The preliminary amendment of paper no. 4, filed March 25, 2002, is acknowledged.

Claims 4 and 6 are amended.

Claims 7-9 are added.

Claims 1-9 are pending and presented for examination.

Priority

The claimed priority of this application to a 371 of PCT/JP00/05922, filed August 31, 2000, and Japan Application 11/244828, filed August 31, 1999, are acknowledged.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

- The Examiner adopts the following rejections in the IPER, form 409 of PCT/JP00/05922:

Claim rejection- 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6 are rejected under **35 U.S.C. 102(b)** as being clearly anticipated by Fuso Yakuhin Kogyo KK (JP-1157911A).

Fuso teaches soft capsules comprising:

- calcium carbonate blended with
- red iron oxide and
- an oil soluble liquid containing vitamin D₃ (abstract, and entire document).

(calcium carbonate is a white pigment).

Claim rejection- 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- Claims 1, 3, and 6 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Fuso Yakuhin Kogyo KK (JP-1157911A) in view of Hegasy et al. (US Patent No. 4,693,892).

Fuso is discussed above.

Fuso does not teach titanium dioxide.

Hegasy et al. teach capsules having an outstanding light protection effect (column 1, line 42; and column 2, lines 23-24) comprising:

- iron oxide (column 2, line 21), and
- titanium oxide (column 2, line 27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add titanium oxide to the capsule composition of Fuso to achieve the beneficial effect of outstanding light protection in view of Hegasy et al.

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- Claims 1, and 3-6 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Fuso Yakuhin Kogyo KK (JP-1157911A) in view of Yamada et al. (JP-63166824 A).

Fuso is discussed above.

Fuso does not teach titanium oxide or glyceride ester.

Yamada et al. teach a transparent or semi-transparent capsule composition having improved light-stability for drugs (abstract, under “purpose”) comprising:

- vitamin D₃ (abstract, and entire document),
- glyceride ester (abstract, and entire document), and
- Titanium oxide (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add titanium oxide and glyceride ester to the composition of Fuso to achieve the beneficial effect of improved light-stability and transparency in view of Yamada et al.

- Claims 1-3, and 9 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Fuso Yakuhin Kogyo KK (JP-1157911A) in view of Sakagami (JP-63166824 A) or Parke Davis & CO (JP-55141242 A).

Fuso is discussed above.

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Fuso does not teach titanium oxide and caramel.

Sakagami et al. teach stable capsules as being resistant to light

(abstract) comprising:

- red iron oxide (abstract),
- titanium oxide (abstract), and
- caramel (abstract, and entire document).

Parke Davis & CO teaches a capsule composition as being

resistant to light (abstract, and entire document) comprising:

- caramel (abstract), and
- Titanium oxide (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add titanium oxide and caramel to the capsule composition of Fuso to achieve the beneficial effect of improved light-stability in view of Sakagami et al. or Park-Davis & CO.

- Claims 1- 9 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Fuso Yakuhin Kogyo KK (JP-1157911A) in view of Sakagami et al. (JP-52151724 A) or Park-Davis & CO, and Yamada et al. (JP-63166824 A).

Fuso is discussed above.

Fuso does not teach titanium oxide and fatty acid glyceride.

Sakagami et al. is discussed above.

Park-Davis & CO is discussed above.

Yamada et al. is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add titanium oxide and caramel, and further, glyceride ester to the capsule composition of Fuso to achieve the beneficial effect of providing resistance to light in view of Sakagami et al. or Park-Davis, and to obtain transparent or semi-transparent capsules in view of Yamada et al. respectively.

Conclusion

Claims 1-9 are rejected.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly

owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Marianne C. Seidel can be reached at (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Helen Nguyen
Patent Examiner

August 21, 2002



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500